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Daniel Thommen

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EXAMINER

TEMPLETON, CHRISTOPHER L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,325	Applicant(s) THOMMEN ET AL.	
	Examiner CHRISTOPHER L. TEMPLETON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-23 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-13 and 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

This office action is responsive to the amendment filed on 28 December 2009. As directed by the amendment: claim 1 has been amended, new claims 17-23 have been added and claim 14 was previously withdrawn. Thus, claims 1, 2 and 4-23 are presently pending in this application.

Response to Arguments

1. Applicant's arguments filed 7 July 2010 have been fully considered but they are not persuasive. Applicant argues that Kotula does not teach a plurality of thin elongate members each having a first and second end. The examiner disagrees. Figures 13-15 and 18 all show thin elongate members. Also page 28, lines 22-24 teaches them as nitinol wires.
2. Applicant also argues that the device of Kotula is not fixable. The examiner again disagrees. The nitinol wires of Kotula fix the occluder into its deployed shape in order to occlude a passage. Applicant never discloses that the occluder is permanently fixable or exactly how much force is needed to overcome a fixed state; therefore Kotula discloses an occluder that has a fixed state. "Fix" means to make firm, stable or stationary (Merriam-Webster), which is what the device of Kotula discloses. Nitinol wires form a fixed state. "Fix" does not mean permanence. Also, the locking mechanism of the applicants can be undone with force.
3. Applicant further argues that the applicant states that "one way to keep the implant in the second state is to attach the two holder to each other...[with] a locking

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mechanism within the specification. The locking mechanism was never claimed in claim 1.

4. Applicant argues that the occluding bodies of Kotula are not attached to the elongate members. The examiner again disagrees. Figures 14, 15 and 18 show the occluding bodies 316 attached to the elongate members. Again, applicant never claims how the occluding bodies are attached to the elongate members.

5. Applicant argues that the occluding body 316 of Kotula cannot be considered an occluding body that closes an internal passage. The examiner disagrees since this was never claimed. No structure is being claimed for the occluding body. The occluding bodies 316 of Kotula can obstruct and block a passage; therefore meeting all claim limitations.

6. Applicant argues that the elongate members of Kotula would not function with Freudenthal's occluding body because Kotula does not have elongate members. The examiner disagrees, since Kotula does have elongate members as discussed above (paragraph 1). Once modified, the elongate members of Kotula would extend through holes in the occluding body. This rejection was a 103 rejection. One of ordinary skill in the art would modify the implant of Kotula to include the membrane, as taught by Freudenthal, for a sealing effect, and elongate members extending through an occluding body, as taught by Solymar, for the purpose of better securing of the occluding member to the elongate members. The holes in the occluding member of Solymar are designed to receive wires, and the elongate members of Kotula are wires.

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Both devices contain wires; therefore the holes can receive the elongate members of Kotula.

7. Applicant argues that there is no motivation or suggestion in the art to combine Chanduszko's locking mechanism with Kotula's device, and that Kotula's disclosure teaches away from the combination. The examiner disagrees. As stated in the rejection, Chanduszko teaches a locking mechanism to hold first and second holders together (Figures 7A-7C) for securing the implant in the deployed state (paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kotula to include a locking mechanism, as taught by Chanduszko, for the purpose of locking the implant in the deployed state to prevent it from inadvertently returning to the first state. The locking mechanism of Chanduszko is releasable (paragraph 66), which does not teach away from the occluder of Kotula being retrievable.

8. Applicant argues the prior art of record fails to disclose new claims 19-23. The examiner disagrees. See rejections of new claims 19-23 below.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 4-11, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotula et al (WO 97/42878).

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11. As to claim 1, Kotula discloses an implant for occluding a passage in a circulatory system (Figures 14, 15 and 18), the implant comprising a plurality of thin elongate members each having a first end and a second end; a first holder 310 to which the first ends of the elongate members are attached; a second holder 308 (Figure 14) to which the second ends of the elongate members are attached, the elongate members being attached to the first and second holders; a first occluding body 316 (Figure 18) being attached to the elongate members. The implant forms in a first state an elongated structure extending along a longitudinal axis (Figure 11), the implant being adapted in the first state for insertion into the circulatory system and the implant being adapted to be brought into a second state (Figures 13, 16 and 17) in the circulatory system, wherein the distance between the holders is capable of being reducible in a manner to cause the elongate members to execute a twisting motion relative to the axis to yield a plurality of generally radially extending loops forming at least one fixation structure, thereby increasing a cross-section of the occluding body and the at least one fixation structure being fixable in the second state, and wherein the implant comprises one second occluding body 316 being attached to the elongate members at a distance to the first occluding body and wherein the distance between the first and the second occluding body is reducible by reducing the distance between the two holders, wherein a fixation structure (a radially extended loop of the elongate members) is formed between the first occluding body and the first holder (Figure 18); wherein the thin elongate members have a first portion 302 being arranged between the first holder 310 and the first occluding body 316 (Figure 14 or 18), a second portion 304 being arranged

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between the second holder and the second occluding body 316 (Figure 18) and a third portion 306 (Figure 14) being arranged between the first and second occluding bodies.

It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

12. As to claim 2, Kotula discloses the first and second fixation structures as being formed in the second state (Figures 13 and 17).

13. As to claim 4, Kotula discloses the first and second portions of the elongate member having approximately the same length (Figure 18).

14. As to claim 5, Kotula discloses the first, second and third portions having approximately the same length (Figure 18).

15. As to claim 6, Kotula discloses the third portions not being twisted like the first and second portions (Figure 17) (when in the second state).

16. As to claim 7, Kotula discloses in the second state the first portion forming a first fixation structure and the second portion forming a second fixation structure (Figure 17).

17. As to claim 8, Kotula discloses in the second state the third portion 306, forming a bended structure with an outer diameter having approximately the same size as the diameter of the cross-section of the first or second occluding body (Figure 17) (it is approximately the same size as applicant's figure 4).

18. As to claim 9, Kotula discloses the implant in the second state wherein the first and the second occluding body 316 have a cross-section having the same size (Figure 18).

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19. As to claims 10 and 11, Kotula discloses the first and the second occluding body 316 being implicitly flexible and disk-shaped in the second state and implicitly compressed in the first state and having a circular shape (Figures 14, 15 and 18).

20. As to claim 13, Kotula discloses the elongate members having the same length Figures 14, 15 and 18).

21. As to claim 17, Kotula discloses the elongate members as wires (nitinol wire) (page 28, lines 22-24).

22. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Freudenthal et al (WO 01/49785). Freudenthal discloses an implant for occluding a passage in a circulatory system, the implant comprising a plurality of thin elongate members 2 each having a first end and a second end; a first holder 1 to which the first ends of the elongate members are attached; a second holder 12 (Figure 7) to which the second ends of the elongate members are attached, the elongate members being attached to the first and second holders; a first occluding body 8 (Figure 7) being attached to the elongate members. The implant forms in a first state (Figure 1) an elongated structure extending along a longitudinal axis, the implant being adapted in the first state for insertion into the circulatory system and the implant being adapted to be brought into a second state (Figure 7) in the circulatory system, wherein the distance between the holders being reducible in a manner to cause the elongate members to execute a twisting motion relative to the axis to yield a plurality of generally radially extending loops forming at least one fixation structure, thereby increasing a cross-section of the occluding body and the at least one fixation structure being fixable in the

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second state, and wherein the implant comprises one second occluding body 8 (page 14, lines 33-37) being attached to the elongate members at a distance to the first occluding body and wherein the distance between the first and the second occluding body is reducible by reducing the distance between the two holders, wherein a fixation structure is formed between the first occluding body and the first holder (Figure 7); wherein the thin elongate members have a first portion being arranged between the first holder 1 and the first occluding body 8, a second portion being arranged between the second holder 12 and the second occluding body 8 and a third portion (Figure 7) being arranged between the first and second occluding bodies (page 14, lines 33-37 discloses the membrane on both sides); wherein the elongate members are only joined together by the first and second holders 1, 12 and by the first and second occluding bodies 8. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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24. Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotula et al (WO 97/42878) in view of Freudenthal et al (WO 01/49785) and further in view of Solymar (U.S. Publication No. 2003/0149463).

25. As to claim 12, Kotula discloses the claimed invention except for the elongate members extending through holes of the occluding body. Freudenthal discloses using a membrane 8 on both sides of an implant for a sealing effect (page 14, line 25-page 15, line 2). Solymar teaches elongate members extending through holes of an occluding body in Figures 11-13. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the implant of Kotula to include the membrane, as taught by Freudenthal, for a sealing effect, and elongate members extending through the occluding body, as taught by Solymar, for the purpose of better securing of the occluding member to the elongate members.

26. As to claim 15, Kotula discloses the claimed invention except for thickened portions arranged on both sides of the first and second occluding bodies. Freudenthal discloses using a membrane 8 on both sides of an implant for a sealing effect (page 14, line 25-page 15, line 2). Solymar teaches thickened portions arranged on both sides of an occluding body for the purpose of capturing and mounting the occluding body (paragraph 49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the implant of Kotula to include the membrane of Freudenthal for a sealing effect, and thickened portions on the elongate members for the purpose of capturing and mounting the occluding body in order to prevent the occluding member from moving.

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27. Claims 16 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotula et al (WO 97/42878) in view of Chanduszko (U.S. Publication No. 2005/0043759).

28. As to claim 16, Kotula discloses the claimed invention but is silent on a locking mechanism to hold the first and second holders together. Chanduszko teaches a locking mechanism to hold first and second holders together (Figures 7A-7C) for securing the implant in the deployed state (paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kotula to include a locking mechanism, as taught by Chanduszko, for the purpose of locking the implant in the deployed state to prevent it from inadvertently returning to the first state.

29. As to claim 19, Kotula discloses an implant for occluding a passage in a circulatory system, the implant comprising a plurality of thin stiff elongate members each having a first and second end; a first holder 310 to which the first ends of the elongate members are attached and a second holder 308 to which the second ends of the elongate members are attached (Figure 14); a first expansible occluding body 316 attached to the elongate members at a point between the first and second holders; a second expansible occluding body 316 attached to the elongate members at another point between the first and second holders and spaced from the first occluding body; said first and second occluding bodies being formed as separate elements from the elongate members (Figure 14); the implant forming in a first state an elongated article extending along a longitudinal axis with the occluding bodies in an unexpanded

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condition (Figure 15), the implant being adapted in the first state for insertion into the circulatory system and the implant being adapted to be brought into a second state (Figure 13) in the circulatory system, wherein the second state is capable of being achieved by causing the holder to move one toward the other to thereby reduce the distance between the holders in a manner to cause the elongate members to execute a twisting motion relative to the axis to yield a plurality of generally radially extending loops about the axis and forming a first and second fixation structure adjacent the first and second occluding bodies, the fixation structures increasing a cross-section of the adjacent occluding body (Figures 15, 14 and 13). Kotula is silent on a mechanism which fixes the at least one fixation structure.

Chanduszko teaches a locking mechanism to fix first and second holders together (Figures 7A-7C) for securing the implant in the deployed state (paragraph 66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kotula to include a locking mechanism, as taught by Chanduszko, for the purpose of locking the implant in the deployed state to prevent it from inadvertently returning to the first state.

It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

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30. As to claim 20, Kotula discloses the first fixation structure being formed between the first occluding body and the first holder and the second fixation structure is formed between the second occluding body and the second holder (Figures 15 and 18).

31. As to claim 21, Kotula discloses the elongate members having first portions being arranged between the first holder 310 and the first occluding body 316 (Figure 15), a second portions being arranged between the second holder 308 and the second occluding body 316, and a third portions being arranged between the first and second occluding bodies, with the first, second and third portions being located in spaced apart relation by the occluding bodies until forming the fixation structures (Figures 15 and 18).

32. As to claim 22, Kotula also discloses the third portion arranged between the first and second occluding bodies twisting into a compressed shape between the first and second occluding bodies in the second state, the first portion forming the first fixation structure and the second portion forming the second fixation structure (Figures 15, 14 and 13).

33. As to claim 23, Kotula also discloses the compressed shape of the third portion being contained within the area of the occluding bodies (Figure 13).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie T. Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./
Examiner, Art Unit 3773

/Julian W. Woo/
Primary Examiner, Art Unit 3773